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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/549,550 | 06/02/2006 | Paula Rachel Yates | 056159-5266-US | 3826 |
| 9629 7590 12/17/2008 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004 | | | | |
| EXAMINER | | | | |
| WOLF, JUSTIN P | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1794 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 12/17/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/549,550

Applicant(s)

YATES, PAULA RACHEL

Examiner

JUSTIN WOLF

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 298)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "comprises genistein/genistin and daidzein/daidzin present in a weight ratio of from 2:1 to 1:2, calculated as aglucon" is indefinite because genistin and daidzin are the glucon forms of the isoflavones and the term "calculated as aglucon" means only the aglucon genistein and daidzein may be present in the composition.

4. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 11 recites the limitation "a food product according to claim 6" in lines 1-2 of claim 11. This phraseology renders claim 11 indefinite because claim 6 is drawn to a composition and not a food product.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (US 2002/0068121) in view of Kuhrts (US 2003/0091656).

Regarding claim 1, Green et al. discloses a blend of quercetin and either one of genistein, daidzein or glycerin isoflavones present in the aglucon form in a ratio of 1:50 to 50:1; quercetin to isoflavones (Abstract; [0008, 0009, 0010]).

Green et al. fails to disclose hops isoalpha acid in the composition.

Kuhrts discloses a pharmaceutical composition comprising isoalpha acids. The isoalpha acids of Kuhrts encompass the use of the unreduced primary iso-alpha acids of humulone, cohumulone, and adhumulone ([0018, 0021]).

It would have been obvious to one of ordinary skill in the anti-inflammatory pharmaceutical art at the time of the invention to modify the composition of Green et al. by substituting the quercetin of Green et al. with the isoalpha acids of Kuhrts because the alpha acids demonstrate anti-inflammatory properties ([0020]). In addition, the

isomerized alpha acids of Kuhrts exhibit more effective joint pain relief and have a shorter onset of action as compared to alpha acids that are not isomerized ([0051, 0052]).

Furthermore, Green et al. discloses the claimed invention except for the use of isoalpha acids. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the quercetin of Green et al. with the isoalpha acid of Kuhrts, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin*, 125 USPQ 416.

Regarding claims 2 and 3, Green et al. discloses a ratio of 1:20 to 20:1 and 1:2 to 2:1 calculated as aglucon for the composition ([0009]).

Regarding claim 4, Green et al. discloses genistein and daidzein in a weight ratio of 2:1 to 1:2 calculated as aglucon ([0010]).

Regarding claim 5, Green et al. discloses the derivation of isoflavones from soy ([0011]).

Regarding claim 6, Kuhrts discloses the use of unreduced iso-alpha acids as stated above.

Regarding claim 7, Green et al. discloses a dosage of 10 to 200mg of quercetin and 10mg to 200mg of isoflavones ([0012]).

Regarding claim 8, Green et al. discloses delivering the dosage via a food product ([0012, 0014]).

Regarding claim 9, Green et al. discloses a food product containing the composition wherein the food product can be delivered 1-5 times per day in order to satisfy the recommended daily intake of the components of the composition ([0013]).

Regarding claim 10, Green et al. discloses the composition present in spreads, margarines, creams, sauces, dressings, mayonnaises, ice creams, fillings, confectionaries, health bars, cereals, or health drinks ([0014]).

Regarding claim 11, Green et al. discloses a food product containing 20mg to 400mg of the composition per recommended serving ([0014]).

Regarding claims 12-17, Green et al. and Kuhrts disclose the applicant's claimed invention and therefore disclose promoting the formation of collagen and/or decorin in the skin, reducing the effects of ageing on the skin, and treating or preventing the effects of inflammation. Furthermore, Green et al. discloses the composition of quercetin and isoflavones for the use of collagen/decorin formation, anti-ageing effects, and anti-inflammatory purposes ([0016, 0017, 0018]). In addition, Green et al. discloses administering an effective amount of the composition according to the recommended daily intake of the components ([0019]).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JUSTIN WOLF whose telephone number is (571)270-7085. The examiner can normally be reached on M-Th 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571)272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. W./
Examiner, Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794